

K062321

510(K) Summary

Submitter: Cynosure, Inc.
5 Carlisle Road
Westford, MA 01886

Contact: George Cho
Senior Vice President of Medical Technology

Date Summary Prepared: August 8, 2006

Device Trade Name: SmartLipo Nd:YAG Laser system

Common Name: Nd:YAG laser

Classification Name: Instrument, surgical, powered, laser
79-GEX
21 CFR 878.4810

Equivalent Device: Laserscope Lyra Series Nd:YAG Laser system

Device Description: The SmartLipo Laser is a Nd:YAG laser system. It emits a 1064nm wavelength.

Laser emission activation is by foot switch. Overall weight of the laser is 180 lbs., and the size is 65" x 23" x 68" (LxWxH).

Electrical requirement is 230 VAC, 15A, 50-60 Hz, single phase.

Intended Use: The SmartLipo laser is intended for the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The SmartLipo is further indicated for laser assisted lipolysis.

Comparison: The SmartLipo laser system has the same indication for use, the same principle of operation, and essentially the same wavelength and pulse energy range as the predicate device.

Nonclinical Performance Data: none

Clinical Performance Data: none

Conclusion: The SmartLipo laser is a safe and effective device for the indicated uses.

Additional Information: none

OCT 31 2006

after PD



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cynosure, Inc.
% Mr. George Cho
Senior Vice President
5 Carlisle Road
Westford, Massachusetts 01886

OCT 31 2006

Re: K062321

Trade/Device Name: Cynosure SmartLipo Laser

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery
and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: October 2, 2006

Received: October 3, 2006

Dear Mr. Cho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

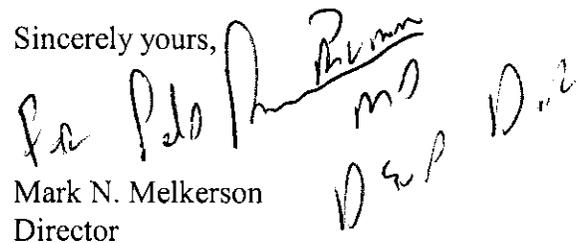
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): R 062321

Device Name: Cynosure SmartLipo Laser

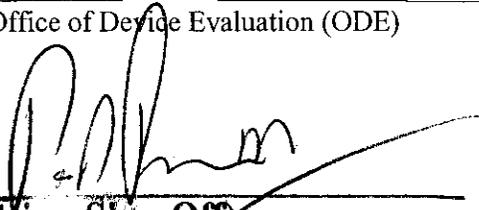
Indications For Use:

The SmartLipo Laser is intended for the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The SmartLipo is further indicated for laser assisted lipolysis.

Prescriptive Use X OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number K062321